PERCEPTIVE MyTrials®

A PAREXEL® eClinical Platform

DATA-DRIVEN MONITORING

CLEARER CONCISE DATA-DRIVEN DECISIONS

KEY FEATURES

- Perform cross-study analysis of quality, risk, and monitoring
- Visualization of site risk & workload data, together with other data relevant to monitoring
- Oversight of monitoring activity decisions during the course of the study
- Initiation of actions/process within the application
- Integration of data from multiple systems such as IMPACT® CTMS, DataLabs® EDC, Safety, ClinPhone® RTSM and third-party applications

BENEFITS

- Enables data-driven decisions around site monitoring activities
- Reduction of on-site monitoring activities and the associated costs
- Improved patient safety and data quality
- Proof to regulatory authorities that adequate monitoring is being performed
- Simpler and cleaner user experience—actions taken directly as a result of data surfaced by the application

Part of the Perceptive MyTrials® framework, enabling integration with clinical trial software applications to help users plan, design and conduct clinical trial programs in a single place

What It Is

Data-Driven Monitoring is a combination of risk-based monitoring, targeted monitoring and centralized monitoring. Essentially, it is the practice of using clinical operations data to guide the "monitoring activities" that are carried out with any given site, as an alternative to regular, scheduled monitoring visits. "Monitoring activities" can be on-site visits, in-house (or centralized) monitoring, data-management activities like data review, or potentially other processes too.

What We Offer

The Perceptive MyTrials® Data-Driven Monitoring platform provides decision support for monitoring activities, supplying an overview of study health from a monitoring perspective. The application assists in the prioritization of monitoring activities and provides tools to help plan and schedule those activities. To support regulatory submissions, decisions

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can be justified by showing data oversight—snapshots of data at the point when actions were taken, proving that monitoring execution was adequate.

About The Solution (Functionality)

The Perceptive MyTrials® Data-Driven Monitoring platform uses powerful data visualizations to help the study team reach data-driven decisions. Shown in both graphical and tabular form, data is presented in an easy-to-consume format, enabling the end user to see a holistic view of data across multiple studies, regions and sites, identify outliers and take action based on those data points. Comprehensive filtering allows the user to tailor their view, allowing each user to see the sites that are important to them today.

Many pharmaceutical companies and CROs are focused on finding ways to quantify risk at a site. Risk can be described as the potential for issues around patient safety and data quality, and even fraudulent behavior. In order to calculate risk, there are a variety of eClinical metrics that can be used. For example, it is possible to identify and quantify serious adverse events, data queries, recruitment rates, withdrawal rates, and so on. Grouping these metrics into risk categories allows the end user to see where there are problem areas at a site that may need corrective action. By using a simple algorithmic approach, data from our eClinical suite can be used to construct a site "risk score," which can be used to identify sites that are at high risk, and use that as a basis for determining the best deployment of monitoring resource.

Risk is not the only consideration when determining the sites that require monitoring. When visiting a site, the monitor is required to carry out a number of key duties. These duties can range from source data verification and drug accountability to a review of the site's regulatory documentation and the follow up of site issues. All of this takes time, which can be quantified in order to determine the workload at the site. By using data from within the Perceptive MyTrials framework, not only can risk be quantified, but so can outstanding workload, giving a more holistic view of how monitoring needs to be managed for any given site.

There are other factors that remain important when determining the best way to manage site monitoring. Maintaining a good site relationship is essential to the success of the study, and it is desirable to visit the site on a regular basis, simply to ensure that the staff are comfortable with the study and that it is progressing smoothly. To that end, even when a risk based approach is being used, the use of time thresholds to determine a minimum level of contact is recommended. Other incidents, such as the achievement of specific study milestones or trigger factors like a serious adverse event may also trigger a site visit. Once a site is identified for further investigation, drilling down allows a view of key risk indicators and outstanding workload, with the addition of other data that may be key in deciding whether to monitor the site. All aspects of monitoring are supported, whether an on-site visit, centralized monitoring or other activities are required.

To comply with GCP, clinical teams must show that adequate study oversight has been provided. With this in mind, Perceptive MyTrials Data-Driven Monitoring includes visualization of data showing changes over time, together with the activities that were carried out by the study team. By combining these two aspects of the data, regulatory authorities and other stakeholders can have full visibility of the fluctuation of risk and outstanding workload over time, and see a full justification for the decisions taken throughout the life of the study, giving peace of mind when it comes to regulatory submission.

Working with other applications in the Perceptive MyTrials framework, monitors can plan, schedule and carry out their monitoring activities seamlessly, with the simple end user experience they have come to expect from an eClinical suite.

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